UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,415	11/21/2001	Anneli Attersand	10806-152	3650

24256 7590 10/04/2004

DINSMORE & SHOHL, LLP
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,415	ATTERSAND, ANNELI	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 10-21 are pending.

Applicants' amendment filed July 15, 2004 is acknowledged. Applicant's response has been considered. Claims 1-9 have been cancelled, and new claims 10-21 have been added. Claim 21 is non-elected invention and is withdrawn from consideration, however, claim 21 will be rejoined with claim 10 upon allowance of claim 10. Therefore, claims 10-20, and SEQ ID NOs:1 and 2 are examined.

Objection Withdrawn

2. The previous objection to the disclosure regarding the embedded hyperlinks is withdrawn in view of applicant's amendment to the specification in the amendment filed July 15, 2004.

3. The previous objection to claims 1 and 3 as to reciting non-elected sequences is withdrawn in view of applicant's amendment to the claim in the amendment filed July 15, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

4. The previous rejection of claims 1-7 and 9, under 35 U.S.C. 101, is withdrawn in view of applicants' cancellation of the claim in the amendment filed July 15, 2004.

Claim Rejections - 35 USC § 112

5. The previous rejection of claims 1-7 and 9, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed July 15, 2004.

Claim Rejections - 35 USC § 102

6. The previous rejection of claims 1, 2, 4-7 and 9, under 35 U.S.C. 102(e) as being anticipated by Tang *et al.* (U. S. Patent 6,569,662, filed July19, 2000), is withdrawn in view of applicants' cancellation of the claim in the amendment filed July 15, 2004.

7. The previous rejection of claims 1-7 and 9, under 35 U.S.C. 102(e) as being anticipated by Leach *et al.* (US 2002/0082206, priority date May 30, 2000), is withdrawn in view of applicants' cancellation of the claim in the amendment filed July 15, 2004.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 10-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a nucleic acid molecule consisting of SEQ ID NO:1 or a nucleotide sequence which is at least 90% homologous to SEQ ID NO:1, or related nucleotides (claims 10 and 19); a polypeptide encoded by the nucleic acid molecule or a polypeptide consisting of SEQ ID NO:2 or a peptide sequence which is at least 90% homologous to SEQ ID NO:2 (claims 11, 12); a vector comprising the nucleic acid molecule (claims 13, 14); a host cell comprising the vector (claims 15 and 17); and a method of producing the polypeptide (claims 16 and 18). However, the function of the protein or the gene encoding the protein has not been identified. The specification indicates the alignment of the proteins in the Protein Cluster I showed a high degree of conservation in two separate regions indicating the presence of two novel domains (Table I, Example 2); the sequence search indicates SEQ ID NO:1 has 88% and 79% sequence

identity, respectively, to two genes that encode a putative rat tricarboxylate carrier protein (page 11, paragraph 4, Example 2); and expression analysis of SEQ ID NO:1 indicates this nucleotide is mainly expressed in the nerve and digestion systems (page 12, Example 3). The related art indicates SEQ ID NO:1 (1232 nucleotides) has 70.6% homology to SEQ ID NO:1343 (1375 nucleotides), and SEQ ID NO:2 (261 amino acids) has 100% sequence identity to SEQ ID NO:1344 (266 amino acids, see sequence match in the previous Office Action; Leach et al., US 2002/0082206), where SEQ ID NO:1344 may be similar to a rat tricarboxylate carrier fragment (page 22); the protein sequence of mitochondria tricarboxylate carrier has 322 amino acids (Azzi et al., 1993); and SEQ ID NO:1 has 76.6% homology to SEQ ID NO:1016 (1729 nucleotides; see sequence match in the previous Office Action; Tang et al., U. S. Patent 6,569,622), where SEQ ID NO:1016 encodes a protein having 99% similarity to a rat tricarboxylate carrier (columns 175-176). However, the specification does not identify the protein of SEQ ID NO:2 as a functional tricarboxylate carrier or as a member of any known protein family, nor demonstrates the activity or function of the protein. Although the specification identifies the tissues having the expression of SEQ ID NO:1, e.g., the tissues of nervous and digestive systems (Example 3), and indicates the invention is to identify genes involved in metabolic disorders (page 3, first paragraph), the direct correlation between the metabolic disorder such as obesity and diabetes and the protein is not demonstrated. For these reasons, the instant invention does not possess a specific and substantial utility or a well-established utility for the claimed polynucleotide and polypeptide, although there is a general utility that is applicable to the broad class of proteins. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use

in an assay to identify modulators of the instant invention, production of antibodies to identify other related proteins or use of polynucleotides to identify other related sequences do not constitute substantial utilities.

In response, applicants indicate that the present specification discloses the genes encode a group of polypeptides which are to be used for the diagnosis of metabolic diseases such as obesity and diabetes, and treatment of such diseases (page 1), the specification discloses that the nucleic acid molecules according to the invention have numerous applications in techniques known to those skilled in the art of molecular biology in diagnosis of obesity and diabetes, as well as in identification of therapeutic agents, including hybridization probes, chromosome and gene mapping, production of sense or anti-sense nucleic acids, screening for new therapeutic molecules, and the like (page 5, lines 4-8); the present specification is specific to the diagnosis and to the identification of agents useful in the treatment of specific metabolic diseases, particularly obesity and diabetes, thus, a specific utility is disclosed; the presently claimed isolated nucleic acid molecule is disclosed as having a correlation to metabolic diseases, particularly obesity and diabetes, and therefore the present specification defines a "real world" context of use in diagnosing these specific diseases and identifying potential candidates for treatment of the diseases, thus, the present specification satisfies the utility guidelines for specific and substantial utility; the disclosed utilities of the presently claimed isolated nucleic acid molecule in the diagnosis of metabolic diseases, specifically obesity and diabetes, as well as in the identification of agents useful in the treatment of such diseases, satisfies the utility requirements of 35 U.S.C. 101 and therefore teaches one skilled in the art how to use the claimed

invention in accordance with the requirements of 35 U.S.C. § 1 12, first paragraph (pages 12-14 of the response).

The response has been considered, however, the argument is not found persuasive because the specification fails to provide the direct correlation between the metabolic disorder such as obesity and diabetes and the claimed polynucleotide and polypeptide, nor provides the guidance necessary for diagnosing and treating metabolic disorder such as obesity and diabetes. MPEP 2107.01 defines a "substantial utility" as a utility that "defines a 'real world' use" and that "utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities." In this case, further experimentation is required to use the claimed polynucleotide and polypeptide for diagnosing and treating the metabolic disorder such as obesity and diabetes. Thus, this type of utility is not considered a "substantial utility". Therefore, the claimed invention does not meet the utility requirement of 35 U.S.C. § 101. Since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 10-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a

well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 10-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-19 are directed to a nucleic acid molecule consisting of SEQ ID NO:1 or a nucleotide sequence which is at least 90% homologous to SEQ ID NO:1, or related nucleotides (claims 10 and 19); a polypeptide encoded by the nucleic acid molecule or a polypeptide consisting of SEQ ID NO:2 or a peptide sequence which is at least 90% homologous to SEQ ID NO:2 (claims 11, 12); a vector comprising the nucleic acid molecule (claims 13, 14); a host cell comprising the vector (claims 15 and 17); and a method of producing the polypeptide (claims 16 and 18). While the specification indicates the present invention provides nucleic acid molecules which is at least 90% homologous to SEQ ID NO:1 (page 4, paragraph 4) and amino acid sequence which is at least 90% homologous to SEQ ID NO:2 (the paragraph bridges pages 5 and 6, lines 9-11), the specification does not disclose a genus of variants for nucleic acid molecules which is at least 90% homologous to SEQ ID NO:1 and amino acid sequence which is at least 90% homologous to SEQ ID NO:2.

The specification indicates the alignment of the proteins in the Protein Cluster I showed a high degree of conservation in two separate regions indicating the presence of two novel domains (Table I, Example 2); the sequence search indicates SEQ ID NO:1 has 88% and 79%

sequence identity, respectively, to two genes that encode a putative rat tricarboxylate carrier protein (page 11, paragraph 4, Example 2); and expression analysis of SEQ ID NO:1 indicates this nucleotide is mainly expressed in the nerve and digestion systems (page 12, Example 3). However, the specification does not describe a genus of variants for nucleic acid molecules which is at least 90% homologous to SEQ ID NO:1 and amino acid sequence which is at least 90% homologous to SEQ ID NO:2. A species of nucleic acid molecule and amino acid sequence (e.g., SEQ ID NOs: 1 and 2) do not provide original descriptive support for a genus of nucleic acid molecules which is at least 90% homologous to SEQ ID NO:1 and amino acid sequence which is at least 90% homologous to SEQ ID NO:2. The variants of SEQ ID NO:1 and 2 do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Applicants have described the nucleotide of SEQ ID NO:1 and the amino acid sequence of SEQ ID NO:2, however, a genus of variants for nucleic acid molecules which is at least 90% homologous to SEQ ID NO:1 and amino acid sequence which is at least 90% homologous to SEQ ID NO:2 have not been described nor disclosed.

The skilled artisan cannot envision all the contemplated nucleotide and amino acid sequences. The detailed structure of the nucleotide and amino acid sequences for variants of SEQ ID NOs:1 and 2 must be taught, therefore conception cannot be not achieved until reduction to

practice has occurred, regardless of the complexity or simplicity of the method of preparation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF'S were found unpatentable due to lack of written description for the broad class.

The claims are drawn to a nucleic acid molecule consisting of SEQ ID NO:1 or a nucleotide sequence which is at least 90% homologous to SEQ ID NO:1, or related nucleotides; a polypeptide encoded by the nucleic acid molecule or a polypeptide consisting of SEQ ID NO:2 or a peptide sequence which is at least 90% homologous to SEQ ID NO:2; a vector comprising the nucleic acid molecule; a host cell comprising the vector; and a method of producing the polypeptide, however, the specification does not provide original descriptive support over the instantly claimed genus of variants for nucleic acid molecules which is at least 90% homologous to SEQ ID NO:1 and amino acid sequence which is at least 90% homologous to SEQ ID NO:2.

Therefore, only those embodiments described and disclosed meet the written description requirement and not the full breadth of the claim meets the written description provision of 35 USC 1 12, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 10, 11 and 13-19 are indefinite because of the use of the term "a nucleotide sequence capable of hybridizing, along its full length, under stringent hybridization conditions, to a nucleotide.....a nucleic acid molecule as defined in (a)". The term cited renders the claim indefinite, it is not clear under what stringent hybridization condition, the full length of the nucleotide sequence is hybridizing to a nucleotide complementary to the polypeptide coding region of a nucleic acid of (a). Claims 11 and 13-19 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

13. Claim 12 is indefinite because the claim depends from a canceled claim, claim 2. See also claim 20.

14. Claim 12 is indefinite because of the use of the term "90% homologous". The term cited renders the claim indefinite, it is not clear whether the term means 90% sequence identity or 90% sequence similarity since the specification does not define the term. For amino acid sequence, the sequence identity is different from sequence similarity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 10, 11 and 13-18 are rejected under 35 U.S.C. 102(e) as anticipated by Tang *et al.* (U. S. Patent 6,569,662, filed July19, 2000).

Tang *et al.* teach an isolated polynucleotide of SEQ ID NO:1016 (1729 nucleotides; columns 175-176) contains a nucleotide sequence (nucleotides 247-1029) encoding SEQ ID NO:2 (see sequence match attached in previous Office Action), and the polynucleotide also includes a nucleotide that hybridizes under stringent hybridization conditions to the complement of SEQ ID NO:1016 (column 3, lines 4-15). Since SEQ ID NO:1016 contains a nucleotide sequence encoding SEQ ID NO:2, a nucleotide sequence that hybridizes under stringent hybridization conditions to the complement of SEQ ID NO:1016 meet the criteria of claim 10(b);

an isolated polypeptide that is encoded by the nucleotide that hybridizes under stringent hybridization conditions to the complement of SEQ ID NO:1016 (column 3, lines 24-32; claim 11); an expression vector containing the nucleotide and a host cell transformed with the expression vector (column 2, lines 47-60; claims 13-15 and 17); and a method of producing a polypeptide by culturing a host cell comprising the vector under conditions to produce the polypeptide (column 3, lines 51-58; claims 16 and 18).

In response, applicants indicate SEQ ID NO: 1016 of Tang et al. contains 1729 nucleotides, while the claimed nucleic acid molecule selected from the group consisting of (a), (b) and (c) as set forth in claim 10 is clearly distinguishable from Tang et al. Thus, Tang et al. provide a significantly larger, different nucleotide sequence, and the patent does not disclose each element of claim 10 (pages 14-15 of the response).

The response has been considered, however, the argument is not persuasive because the patent discloses SEQ ID NO:1016 contains a nucleotide sequence (nucleotides 247-1029) encoding SEQ ID NO:2, a nucleotide that hybridizes under stringent hybridization conditions to the complement of SEQ ID NO:1016 is not distinguishable from the nucleic acid molecule of claim 10(b) consisting essentially of (reads as comprising) a nucleotide capable of hybridizing, along its full length (can be any length), under stringent hybridization conditions to the complement of polypeptide coding region of SEQ ID NO:1. Therefore, the patent anticipate the claimed invention.

16. Claims 10, 11 and 13-18 are rejected under 35 U.S.C. 102(e) as anticipated by Leach *et al.* (US 2002/0082206, priority date May 30, 2000).

Leach *et al.* teach an isolated polynucleotide of SEQ ID NO:1343 (1375 nucleotides; paragraph [0005]) and an isolated polypeptide SEQ ID NO:1344 (266 amino acid) encoded by the nucleic acid sequence (paragraph [0009]), where SEQ ID NO:1344 has 100% sequence identity to SEQ ID NO:2 (261 amino acids; see sequence match attached in the previous Office Action; column 3, lines 24-32). Since claim 10(b) recites "consisting essentially of" (reads as comprising), the claimed nucleic acid molecule of claim 10(b) comprises a nucleotide sequence which full length (can be any length) hybridizes under stringent hybridization conditions to the complement of polypeptide coding region of SEQ ID NO:1, and SEQ ID NO:1343 encodes a polypeptide having SEQ ID NO:2 (claim 11), it would be expected that the polynucleotide of SEQ ID NO:1343 comprises a nucleotide which full length hybridizing under stringent hybridization conditions to the complement of the polypeptide coding region of SEQ ID NO:1 (claim 10(b)); an expression vector containing the nucleotide and a host cell transformed with the expression vector (paragraphs [0006] and [0007]; claims 13-15 and 17); and a method of producing a polypeptide by culturing a host cell comprising the vector under conditions to produce the polypeptide (paragraph [00012]; claims 16 and 18).

In response, applicants indicate the present application has a priority date of November 24, 2000, while Leach et al. claims priority to provisional application 60/208,427 filed May 30, 2000, the Examiner has not demonstrated that the Leach et al provisional application contains the disclosures relied upon by the Examiner in rejecting the claims of this application; and SEQ ID NO: 1343 of Leach et al. contains 1375 nucleotides, while the claimed nucleic acid molecule selected from the group consisting of (a), (b) and (c) as set forth in claim 10 is clearly distinguishable from Leach et al. Thus, Leach et al. provide a significantly larger, different

nucleotide sequence, and the patent does not disclose each element of claim 10 (pages 15-16 of the response).

The response has been considered, however, the argument is not persuasive because the provisional application 60/208,427 discloses SEQ ID NOs: 1343 and 1344 (see attached Table, No. 396); and the patent discloses SEQ ID NO:1343 contains a nucleotide sequence encoding SEQ ID NO:1344 (266 amino acids) which has 100% sequence identity to SEQ ID NO:2 (261 amino acids), thus, the polynucleotide of SEQ ID NO:1343 is not distinguishable from the nucleic acid molecule of claim 10(b) consisting essentially of (reads as comprising) a nucleotide capable of hybridizing, along its full length (can be any length), under stringent hybridization conditions to the complement of polypeptide coding region of SEQ ID NO:1. Therefore, the patent anticipate the claimed invention.

17. Claim 12 is rejected under 35 U.S.C. 102(a) as being anticipated by Shimkets *et al.* (WO 200058473, October 30, 2000). The document of WO 200058473 is not provided because of its length (5509 pages).

Shimkets *et al.* teach a human ORFX polypeptide (SEQ ID NO:2706) which contains 251 amino acids and has 94.3% sequence identity to SEQ ID NO:2 (see attached sequence match; claim 12).

Conclusion

18. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
September 21, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER